

**UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION**

<b>IN RE NATIONAL PRESCRIPTION</b>	)	
<b>OPIATE LITIGATION</b>	)	<b>MDL No. 2804</b>
	)	
<b>THIS DOCUMENT RELATES TO:</b>	)	<b>Case No. 1:17-md-2804</b>
	)	
<b><i>ALL CASES</i></b>	)	<b>Hon. Dan Aaron Polster</b>
	)	
	)	
	)	

**CERTAIN DEFENDANTS’ OPPOSITION TO PLAINTIFFS’ MOTION TO LIFT  
MORATORIUM ON SUBSTANTIVE FILINGS TO PERMIT PLAINTIFFS TO FILE  
MOTIONS FOR LEAVE TO AMEND TO ADD DEFENDANTS**

The undersigned Defendants respectfully submit this response to the Plaintiffs’ Executive Committee’s (“PEC” or “Plaintiffs”) Motion to Lift Moratorium on Substantive Filings to Permit Plaintiff to File Motions for Leave to Amend to Add Defendants (“Motion”).

*First*, Plaintiffs have offered no basis for lifting the moratorium to file motions for leave to amend in non-bellwether cases, and the request should be denied. Further, Plaintiffs’ proposal would only expand this MDL at a time when the Court and parties should be focused on narrowing the remaining cases and claims.

*Second*, to the extent that the Court grants the request to lift the moratorium, Plaintiffs should not be permitted to file an omnibus motion seeking across-the-board leave to add additional defendants to pending cases, which would violate Rules 15 and 16 of the Federal Rules of Civil Procedure. Rather, consistent with the Sixth Circuit’s determination *In Nat’l Prescription Opiate Litig.*, 956 F.3d 838 (6th Cir. 2020) that the “rule of law applies in multidistrict litigation . . . just as it does in any individual case,” *id.* at 841, Plaintiffs must file any motions for leave to amend on a case-by-case basis and must provide specific arguments for each amendment they seek.

## ARGUMENT

### **I. THERE IS NO BASIS TO LIFT THE MORATORIUM BECAUSE THE COURT HAS MADE CLEAR THAT MOTIONS FOR LEAVE TO AMEND MAY ONLY BE FILED IN BELLWETHER CASES.**

The Court has made clear on several occasions that motions for leave to amend complaints are reserved for cases that have been selected as bellwethers. Plaintiffs seek to upend that process without adequate basis, offering as putative justification only that they seek additional leverage in settlement negotiations. *See* Mot. at 2 n.1. This is not a sufficient basis to depart from the Court’s numerous orders establishing the parameters for requests to amend.

Early in the MDL, this Court put a moratorium on substantive filings. *See* Dkt. 70 at 2; Dkt. 4 at 4; Dkt. 130. The moratorium prevented the parties from filing any substantive motion – including filings by plaintiffs amending or seeking leave to amend their complaints. *Id.* This moratorium has been lifted to entertain an amended complaint process *only* (1) when the ARCOS data first became available and (2) when cases have been selected as bellwethers.

As to the ARCOS data exception, in 2018, after the Court ordered the United States Drug Enforcement Administration (“DEA”) to produce ARCOS data, the court lifted its moratorium for the purpose of allowing MDL plaintiffs to amend their complaints based upon the ARCOS data. Dkt. 1106. The deadline to amend Plaintiffs’ complaints under the Court’s Case Management Order (“CMO-1”) was March 16, 2019. *Id.*<sup>1</sup> Though the Court did extend the production of ARCOS data in July 2023 to encompass additional years, it did not extend a simultaneous opportunity for amendment. In fact, just the opposite: the Court expressed that “to amend

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<sup>1</sup> This deadline had been previously extended on multiple occasions, including twice before at the request of Plaintiffs. The Court’s original scheduling order set forth May 25, 2018, as Plaintiffs’ deadline to amend. *See* Dkt. 232 at 9. On July 13, 2018, the Court granted Plaintiffs’ motion for modification of CMO-1, allowing Plaintiffs’ additional time to file amended complaints on or before November 16, 2018. Dkt. 739. On November 8, 2018, the Court granted another Motion for Modification of CMO-1 brought by Plaintiffs, extending the deadline to amend to their complaints to March 16, 2019. Dkt. 1106.

complaints years after their cases were filed and made part of this MDL” would “raise some real concern.” Dkt. 5115 at 12 (citing *In re Nat’l Prescription Opiate Litig.*, 956 F.3d at 843). The Court further stated that if Plaintiffs ultimately moved to amend complaints, “the Court [would] rule on those motions based on the Federal Rules of Civil Procedure, the arguments and case-law provided in the parties’ briefs, and the guidance provided by the Sixth Circuit in its mandamus rulings.” *Id.*; see *In re Nat’l Prescription Opiate Litig.*, 956 F.3d at 843 (granting mandamus relief where this MDL Court granted a motion to amend the complaint “long after the deadline set by the court’s scheduling order”) and *In re Nat’l Prescription Opiate Litig.*, No. 21-4051, 2022 WL 20701236, at \*1 (6th Cir. Nov. 10, 2022) (“*Meijer*”) (denying mandamus relief where this MDL Court granted a motion to amend the complaint in a case after it was selected as a bellwether, but noting “the order went right to the edge of the district court’s discretion under Rule 16.”).

As for the bellwether case exception, in granting Plaintiffs’ motion for leave to amend complaints in the PBM bellwether cases, the Court explained that amendments were permitted pursuant to the Court’s “Short Form Complaint Order” (see Dkt. 1282, January 18, 2019) of years prior, noting that the Short Form Complaint Order “expressly provided that, ‘should any of those cases subsequently be set for trial, purported deficiencies with the complaints can be addressed at the time by subsequent Court order.’” Dkt. 5319 at 2-3 (quoting Short Form Complaint Order at 3). Importantly, the Court noted that: “At **all** other times, no MDL plaintiff could amend its complaint without first being selected as a bellwether.” *Id.* (emphasis in original). As an example, the court cited Webb County, now the Plaintiff in Track 15, which had unsuccessfully moved for leave to amend its complaint prior to being selected as a bellwether. *Id.* at n.3 (citing Dkt. 4896 and March 20, 2023 non-document Order); see also Dkt. 5225 (citing *Meijer* and permitting proposed Case Management Orders for TPP bellwether cases to include a deadline for amendment

of complaints only *after* cases were selected as TPP bellwethers); Dkt. 5231 (same for cases selected as PBM bellwethers).

Plaintiffs have not demonstrated circumstances that would justify lifting the moratorium to permit them an opportunity to seek leave to amend their complaints, particularly given the time that has elapsed in the MDL and the narrow grounds upon which the Court has previously granted leave to amend. Indeed, as discussed further below, Plaintiffs' motion offers no clarity about the specifics of the amendments they intend to request, let alone why the moratorium should be lifted to allow them to seek those specific amendments. Notably, Plaintiffs do not claim that they intend to seek amendments as part of any bellwether track; to the contrary, they state openly that they intend to seek permission to amend for the purpose of leverage – not litigation.

Moreover, Plaintiffs' proposal seeks to expand the MDL at a time when the parties and the Court should be working to narrow it. On November 9, 2022, the Court requested the remaining defendants and the PEC provide "suggestions on mechanics to winnow and resolve remaining cases and claims," including the use of *Lone Pine* Orders. Dkt. 4742. Various Defendant groups submitted well-reasoned proposals to assist with winnowing of cases. *See, e.g.*, Remaining Distributors' Dec. 7 Status Report and Proposal for Case Management and *Lone Pine* Order; Certain Remaining Manufacturer Defendants' Dec. 7 Status Report and Case Management Proposal.<sup>2</sup> The PEC resisted entry of any meaningful case management or *Lone Pine* Orders, and proposed merely that the PEC would "provide the Court with an analysis of the Tier 2 and Tier 3 defendants, based on the review of data currently in the PEC's possession . . . ." PEC's Dec. 7 Position Statement. Since then, the PEC has not offered any material manner through which to

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<sup>2</sup> Subsequently, the Court undertook certain processes designed to winnow cases that had not been diligently pursued. *See, e.g.*, Dkt. 4801 (Order Regarding Plaintiff Fact Sheets and Service of Process); Dkt. 5382 (Marginal Entry Order granting Defendants' Motion to Dismiss Certain Hospital Plaintiffs for Failure to Submit Fact Sheets).

“winnow and resolve remaining cases and claims.” Instead, the PEC seeks to *expand* the MDL by the addition of defendants through an omnibus motion for leave. Such an approach is neither fitting nor productive for this mature MDL. The Court should deny Plaintiffs’ Motion to lift the moratorium, and instead revisit the *Lone Pine* suggestions — including the imposition of market share thresholds—made by Defendants that seek to winnow and resolve the remaining cases and claims.<sup>3</sup>

**II. IF THE COURT LIFTS THE MORATORIUM, PLAINTIFFS’ MOTIONS FOR LEAVE MUST ESTABLISH THE REQUIREMENTS OF RULE 15 AND RULE 16 FOR EACH CASE IN WHICH THEY SEEK LEAVE TO AMEND.**

To the extent the Court is inclined to lift the moratorium to permit Plaintiffs to seek leave to amend their Complaints, Defendants request that Plaintiffs be required to file individual motions for leave in each case in which they seek amendment, with the specific details of which defendants they intend to add as well as those they intend to drop<sup>4</sup> and the putative basis for each defendant they seek to add – including, if they intend to rely on ARCOS data, why they did not identify the defendant proposed to be added based on the prior years’ of ARCOS data made available in 2018.

Plaintiffs’ Motion to lift the moratorium leaves the impression that Plaintiffs may intend to seek omnibus permission to amend any and all cases to add defendants whenever they see fit to do so. Indeed, they allude generally to “many [] plaintiffs” who “would add additional defendants, including PBMs, other pending bellwether defendants, or Tier 2/Tier 3 defendants to their existing

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<sup>3</sup> Ordering the PEC to engage in meaningful analysis of their cases pursuant to specific *Lone Pine* requirements would also provide a natural framework through which the PEC could more appropriately move for leave to amend additional defendants into individual cases. Denying the Plaintiffs’ request without prejudice and requiring the PEC to first meaningfully scrutinize its portfolio of cases would be far more productive in driving the parties and claims towards resolution than permitting Plaintiffs to file for leave to amend.

<sup>4</sup> As the Court made clear to the parties at the April 24, 2024 status conference, any permitted amendment to add defendants to existing cases should occur in conjunction with dismissals of defendants, in furtherance of the goal of moving cases and this overall litigation towards resolution rather than unfettered expansion of the scope of this MDL and the cases in it.

cases if they were granted leave to do so.” Mot. at 2. They do not reference any limitations on or threshold grounds required for amendment to add defendants to an existing and long-pending lawsuit.

But an omnibus motion purporting to address the amendment requests of each of these “many” plaintiffs and the varying “additional defendants” they may seek to add across numerous defendant groups could not comply with Rules 15 and 16 of the Federal Rules of Civil Procedure. Rule 15 provides that “[t]he court should freely give leave” to amend a pleading “when justice so requires.” Fed. R. Civ. P. 15(a)(2). “In deciding whether to grant a motion to amend, courts should consider undue delay in filing, lack of notice to the opposing party, bad faith by the moving party, repeated failure to cure deficiencies by previous amendments, undue prejudice to the opposing party, and futility of amendment.” *Brumbalough v. Camelot Care Ctrs., Inc.*, 427 F.3d 996, 1001 (6th Cir. 2005). This inquiry is necessarily case-specific. So too is the inquiry under Rule 16. *See, e.g., Commerce Benefits Grp. Inc. v. McKesson Corp.*, 326 F. App’x 369, 376 (6th Cir. 2009) (“Once the scheduling order’s deadline to amend the complaint passes, however, ‘a plaintiff first must show good cause under Rule 16(b) for failure earlier to seek leave to amend’ and the district court must evaluate prejudice to the nonmoving party ‘before a court will [even] consider whether amendment is proper under Rule 15(a).’”) (internal citations omitted) (emphasis added).

Nor would an omnibus motion be appropriate at this late stage of litigation in this MDL. In *In re Nat’l Prescription Opiate Litigation*, the Sixth Circuit made this clear in granting a writ of mandamus to the Pharmacy Defendants in the “Track One” litigation and denying Plaintiffs’ attempt to amend their complaints well after the deadline to do so had passed. As the Sixth Circuit stated:

The rule of law applies in multidistrict litigation under 28 U.S.C. § 1407 just as it does in any individual case. Nothing in § 1407 provides any reason to conclude otherwise. Moreover, as the Supreme Court has made clear, every case in an MDL (other than cases for which there is a consolidated complaint) retains its individual character. That means an

MDL court's determination of the parties' rights in an individual case must be based on the same legal rules that apply in other cases, as applied to the record in that case alone. Within the limits of those rules, of course, an MDL court has broad discretion to create efficiencies and avoid duplication—of both effort and expenditure—across cases within the MDL. What an MDL court may not do, however, is distort or disregard the rules of law applicable to each of those cases.

*Id.* 956 F.3d at 841. Given the similar case posture here, this Court should reject Plaintiffs' attempt to undermine the "individual character" of each case by bringing a collective motion for leave to amend across cases, in which Plaintiffs seek leave to add potentially dozens of defendants into hundreds or even thousands of lawsuits without any justification for why they did not name such defendants previously, and without any requirement that Plaintiffs demonstrate a good faith reason to amend as to any particular defendant or case. To do otherwise would frustrate Defendants' entitlement to notice and their ability to meaningfully respond. At present, no defendant is on notice as to whether it would potentially be added to cases if permitted, and if so, which ones or how many cases.

Accordingly, to the extent the Court grants Plaintiffs' Motion to lift the moratorium, Defendants request that Plaintiffs' forthcoming motions for leave to amend be filed on an individual case-by-case basis. The defendants that Plaintiffs seek to add in an individual case will thereby be put on notice of the Plaintiffs' request to add them to each particular case and have a meaningful opportunity to respond to such request(s) in each individual case.

### **CONCLUSION**

For the foregoing reasons, Defendants request that the Court deny Plaintiffs' Motion to Lift Moratorium on Substantive Filings to Permit Plaintiff to File Motions for Leave to Amend to Add Defendants. In the alternative, if the Court is inclined to lift the moratorium to permit Plaintiffs to seek leave to amend, Defendants request that Plaintiffs be required to file individual motions for leave on a case-by-case basis that provide specific arguments for amendment.

Dated: May 6, 2024

Respectfully Submitted,

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**CERTIFICATE OF SERVICE**

I, Francis A. Citera, an attorney, certify that I caused a copy of the foregoing Opposition To Plaintiffs' Motion To Lift Moratorium On Substantive Filings To Permit Plaintiff To File Motions For Leave To Amend To Add Defendants to be served upon the parties of record using the CM/ECF system which will send notification of such filing on this May 6, 2024.

/s/ Francis A. Citera

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